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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,872	08/27/2001	Jean Ackermann	20757	4842

151 7590 04/02/2003

HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
340 KINGSLAND STREET  
NUTLEY, NJ 07110

EXAMINER
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AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 04/02/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/939,872

Applicant(s)

Ackermann, J. et al.

Examiner

CHARANJIT AULAKH

Art Unit

1625

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Feb. 10, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-58 and 60-75 is/are pending in the application.
- 4a) Of the above, claim(s) 9, 28-41, and 64-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-27, 42-46, 48, 50, 52, 57, 60, 62, 63, 67, 69, 70, and 72-75 is/are rejected.
- 7) ☒ Claim(s) 47, 49, 51, 53-56, 58, 61, 68, and 71 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

Art Unit: 1625

### **DETAILED ACTION**

1. Claims 1-58 and 60-75 are pending in the application. Claims 9, 28-41 and 64-66 are withdrawn from further consideration as being directed to non-elected inventions.

#### ***Response to Arguments***

2. Applicant's arguments filed on Feb.10, 2003 ( paper no. 13 ) regarding Improper Markush Group as well as indefiniteness have been fully considered but they are not persuasive. The restriction was made final in the last office action. Therefore, the applicants should either petition the restriction requirement or amend the claims to read upon the elected group.

In regard to indefiniteness of the term --esters---, the examiner does not agree with the applicants arguments that the specification teaches preparing esters of the instant compounds. There is not even a single example showing esters of the instant compounds in the specification. There is no teaching in the specification that esters prepared from the instant compounds having optionally substituted variables with hydroxy groups will work effectively in vivo. The applicants mention that there are several U.S. Patents issued with this term. However, the applicants have not provided a single patent to validate their argument where this term appears in the claims without adequate support in the specification.

In regard to prior art rejection, the examiner agrees with the applicants arguments that the instant compounds are not anticipated but are structural homologues of the compounds disclosed by Aebi.

Art Unit: 1625

*Conclusion*

3. Rejections of claims 1-8, 10-27, 42, 45, 46, 48, 50, 52, 57, 60, 62, 63, 67, 69, 70 and 72-75

under 35 U.S.C. 112, second paragraph is maintained for the reasons of record.

4. Objections of claims 1-7, 10-27, 42, 60, 62, 63 and 73-75 due to Improper Markush Group is maintained for the reasons of record.

5. Rejection under 35 U.S.C. 102(a) is now withdrawn.

NEW GROUNDS OF REJECTION

*Claim Rejections - 35 USC § 112*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 75 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while

being enabling for treating hypercholesterolemia, hyperlipemia and arteriosclerosis, does not

reasonably provide enablement for treating all other diseases such as mycoses, parasitic

infections, gallstones, tumors, vascular diseases or hyperproliferative disorders. The

specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to use the invention commensurate in scope with these claims. The

following eight different factors ( see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F.

Art Unit: 1625

2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988 ) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples and the state of the prior art.

The instant compounds are inhibitors of OSC as mentioned on page 33. The specification teaches on pages 2-3 that inhibitors of OSC are known to lower cholesterol levels and therefore the instant compounds will have utility in treating hypercholesterolemia, hyperlipemia and arteriosclerosis. However, there is no teaching either in the specification or prior art that OSC is involved in the etiology of mycoses, parasitic infections, gallstones, tumors, vascular diseases or hyperproliferative disorders. There are no working examples to show how the instant compounds having inhibitory activity against OSC will treat all these disorders. In absence of such teachings, guidance or suggestion in the specification or prior art, it would require undue experimentation to demonstrate the effectiveness of the instant compounds in treating diseases other than hypercholesterolemia, hyperlipemia and arteriosclerosis.

Art Unit: 1625

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3, 6, 10-27, 42-44 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al.( U.S. Patent no. 6,034,275 ).

Aebi discloses tertiary amines. The compounds of formula Ie ( see column 10, lines 40-60 as well as examples 49 and 50 ) and a method of using them for treating various disorders ( see col. 22, lines 54-64 ) disclosed by Aebi are structural homologues of the instant claims when W or X represents SO<sub>2</sub>, n is 0 and V represents O in the instant compounds of formulae (I) and (Ia) since they differ only by one CH<sub>2</sub> group when m or p represents 2-3 in the instant compounds of formulae (I) or (Ia), respectively. It is of note that the compounds of Aebi et al. have identical utility as the instant compounds of inhibiting OSC activity. Therefore, it would have been obvious to one skilled in the art to prepare the instant compounds without affecting their utility of inhibiting OSC activity since structural homologues are well known in the prior art to share the same properties.

Art Unit: 1625

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chana Aulakh whose telephone number is (703) 305-4482. The examiner can normally be reached on " Monday-Thursday " from 7:30 A.M. to 6:00 P.M.

If the attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Alan Rotman, can be reached on (703) 308-4698. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist whose telephone number is (703) 308-1235.

  
CHARANJIT S. AULAKH

PRIMARY EXAMINER